



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 09/989,420 | 11/21/2001 | Junichi Mineno | 1422-0506P | 9784 |
| 2292 | 7590 | 06/29/2004 | EXAMINER | |
| BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747 | | | SIEW, JEFFREY | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1637 | |

DATE MAILED: 06/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/989,420

Applicant(s)

MINENO ET AL.

Examiner

Jeffrey Siew

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 April 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 1-6 and 22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. This application contains claims 1-6 & 22 are drawn to an invention nonelected with traverse in the reply filed on 8/6/03. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Art Unit: 1637

Claims 7-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lucito et al (PNAS vol. 95 pp. 4487-4492 1998) in view of Thorstenson et al (Genome Research vo. 8 No. 8 pp. 848-855 1998).

Lucito et al teach the formation of libraries by fragmenting DNA and using PCR to amplify the mixture (see whole doc. esp. abstract). They use T4 DNA polymerase.

Lucito do not teach sheering.

Thorstenson teach shearing where 90% of sheared DNA fragments fall within a two fold size distribution. (see whole doc. esp. abstract).

One of ordinary skill in the art would have been motivated to apply Thorstenson et al's shearing to Lucito et al's library construction method in order to increase the fragmentation of genomic DNA. Thorstenson states that shearing allows for more random fragmentation which would be useful in shot gun sequencing. It would have been prima facie obvious to apply Thorstenson's shearing approach to Lucito et al's library construction to provide a more random and thorough fragmentation.

3. The response filed 4/8/04 has been fully considered and found not persuasive. The response states that the combination of references does not teach or suggest that size convergence rate of not less than 80% or distribution ratio of 1 to 5 as defined by size ratio of the maximum size to minimum size fragmented DNA . Thorstenson does teach a convergence rate of 90% within the size range that was 2.0 fold (see page 852). They also teach having a distribution ratio of 1 to 5 (see Figure 7). Moreover, the response states that no motivation would exist because the Thorstenson et al's method would result in bias for small average size

Art Unit: 1637

which would not satisfy the limitation that the construction maintains copy members for a set of genes and maintain abundance ratio of set of genes or sequences. The term “a set of genes” reads broadly and does not read on all the genes of the genome but would read on any set, not necessarily the complete set of genes in the genome. As Thorstenson et al’s method does result in a distribution that is representative of some set, Thorenston et al method would meet the limitation. Moreover, Thorenston et al does state that the cloning efficiency is very good and distribution of assembled sequences is random and no sequence bias at ends of sheared fragments that have been cloned (see abstract). In the declaration, the response states that the present invention provides excellent maintenance of copy of genes preferably 85% to 95% or more. However, the limitation of “85% to 95% or more” is not recited in the claims. Thorenston et al’s method would still be expected to provide at least “excellent” maintenance as they teach that the cloning efficiency is very good and distribution of assembled sequences is random and no sequence bias at ends of sheared fragments that have been cloned (see abstract). The rejection is maintained. A possible avenue to overcome the cited prior art would be to insert a numerical percentage of the number of genes from the total genome that are maintained. However, new consideration and/or search may be required.

SUMMARY

4. No claims allowed.

Conclusion

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Siew who can be reached at 571-272-0787. The e-mail address is Jeffrey.Siew@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route. The examiner is on flex-time schedule and can best be reached on weekdays from 6:30 a.m. to 3 p.m. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (571)272-0782.

Art Unit: 1637

Any inquiry of a general nature, matching or filed papers or relating to the status of this application or proceeding should be directed to the Tracey Johnson for Art Unit 1637 whose telephone number is (571)272-0534.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The 1600 Tech Center FAX is (703)-872-9306.


JEFFREY SIEW
PRIMARY EXAMINER

June 23, 2004